

Appl. No. : 10/649,480  
Filed : August 27, 2003

### AMENDMENTS TO THE CLAIMS

Claim 1. (Currently amended) A method for ~~revascularizing~~ increasing cardiac efficiency of a heart having an ischemic myocardial region in a human subject, comprising the steps of:

(a) preparing a pharmaceutical composition comprising a recombinant fibroblast growth factor-1 (FGF-1); and

(b) injecting an amount of said pharmaceutical composition into the ischemic region of the myocardium, said amount being sufficient to induce local neoangiogenesis; and

(c) ~~evaluating and whereby~~ at least one clinical index of cardiac function is enhanced in the human subject to confirm that cardiac efficiency has increased.

Claims 2-19. (Cancelled)

Claim 20. (Previously presented) The method of Claim 1, wherein said FGF-1 is injected at a final concentration in a range of about 0.1 µg/kg body weight per site to about 10 µg/kg body weight per site.

Claim 21. (Original) The method of Claim 1 wherein said FGF-1 is injected at a final concentration in a range of about 10 to 100 µg/kg body weight per site.

Claim 22. (Original) The method of claim 1, wherein the pharmaceutical composition further comprises a physiologic glue.

Claim 23. (Original) The method of Claim 22, wherein said physiologic glue is fibrin glue.

Claim 24. (Original) The method of Claim 1, wherein said FGF-1 and said physiologic glue are mixed immediately prior to application.

Claim 25. (Original) The method of Claim 1, wherein said pharmaceutical composition further comprises an anticoagulant.

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Claim 26. (Previously presented) The method of Claim 25, wherein said anticoagulant is heparin.

Claim 27. (Original) The method of Claim 26, wherein the heparin is applied at a final concentration in a range of about 1 U per ml to about 1000 U per ml.

Claim 28. (Previously presented) The method of Claim 1, wherein said injecting step further comprises:

- making a thoracotomy incision;
- identifying at least one site of coronary artery stenosis;
- administering a  $\beta$ -blocker to reduce the heart rate to a range of about 20-60 beats per minute; and
- injecting the pharmaceutical composition intramyocardially at or near the at least one site of coronary artery stenosis.

Claim 29. (Original) The method of Claim 28, wherein said thoracotomy incision further comprises an anterior left-sided incision; dissecting a region of costal cartilage over a 5<sup>th</sup> rib; and opening a left pleural space and a pericardium.

Claim 30. (Original) The method of Claim 28, wherein the step of identifying the at least one site of coronary artery stenosis further comprises retracting the heart forward using traction sutures.

Claim 31. (Original) The method of claim 1, wherein the neoangiogenesis is long term and occurs in the ischemic region at 6 weeks after the injection.

Claim 32. (Original) The method of claim 1, wherein the neoangiogenesis is long term and occurs in the ischemic region at 3 months after the injection.

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Claim 33. (Original) The method of claim 1, wherein the method further comprises performing a coronary artery bypass graft.

Claim 34. (Original) The method of claim 1, further comprising the step of injecting a composition comprising a physiologic glue subsequent to injection with the pharmaceutical composition.

Claim 35. (Cancelled)

Claim 36. (Previously presented) The method of claim 1, wherein the ischemic region comprises at least one site in a heart wall.

Claim 37. (Cancelled)